REMARKS

The foregoing amendment in claim 1 is intended to make is clearer that the thermoformability and stability of the edible layer of the claimed pharmaceutical dosage form are characteristic of the diffraction relief.

Applicant respectfully traverses the rejection of claims 1-5, 7, and 9-28 under 35 USC 103(a) in view of Applicant's European Patent No. 0 217 821 ("EP'821") and Applicant's 1991 SPIE article, "Edible Holography," termed by the Examiner, "Begleiter II."

The Examiner cites Begleiter I as teaching "an edible holographic element comprising a polymer such as hydroxypropylmethylcellulose (Col. 2, lines 13-30)" and a "plasticizer such as polyhydric alcohol and dextrose (Col. 2, line 49 through Col. 3, lines 1-33)."

The Examiner refers to the use of polyhydrolic alcohol and dextrose in Begleiter I as teaching the claimed invention. However, "plasticizer" appears only in claim 23, and only as a material that can be met to produce a diffraction relief whose performance provides a visible indication of the product history and efficacy vis-à-vis moisture (humidity). In fact, the present application teaches away from such plasticizers as thermoformed (vs. dehydrated) holograms. The specification states that plasticizers such as propylene glycol, and sweeteners such as lactose, increase the effects of moisture on the layer 12 and the diffraction relief it carries. By varying the amount and type of such hygroscopic materials, one can readily vary the hygroscopic nature of the coating, making it more likely to swell in humid weather. The overall hygroscopic swelling of the coating on the scale of the wavelength of light will change the relief pattern sufficiently to be visible through changes in the effect produced by the diffraction relief.

The Examiner agrees that Begleiter I does not teach a "pharmaceutical dosage form comprising active substance." She cites Begleiter II for teaching "a holographic composition for compressed candies, children's vitamins, and form of brand

identification (page 104)," and as "a holographic composition comprising cellulose such as HPMC (page 103)." The Examiner concludes that the claimed pharmaceutical dosage form "would have been obvious to one of ordinary skill in the art from these teachings."

The only mention in the prior art of a pharmaceutical with holographic effect capabilities is the experiment mentioned on page 104, top, of Begleiter II. This teaching tells one of ordinary skill in the art that to make a pharmaceutical dosage form, one does not use the teachings of Begleiter I, or the other approaches described in Begleiter II to make confections or the like. Rather, Begleiter II teaches to cold compress a powder into a tablet with a diffraction relief formed in the compressed powder by a die in the press. The resulting end product is a pharmaceutical dosage form, but it is not the product presently claimed. It has no layer containing a diffraction relief, it has no layer that is thermoformable to receive a diffraction relief, and it is not stable. Begleiter II teaches away from a combination of Begleiter I and Begleiter II to produce a pharmaceutical dosage form.

The Examiner also cites Begleiter I and Begleiter II as teaching the use of HPMC. However, as described in Begleiter I, and as stated at the cited page 103 of Begleiter II, "complex polysaccharides [including modified celluloses] which have been used as those which can be dehydrated from a liquid solution." The cited prior art therefore teaches away from the use of HPMC as a thermoformable layer that receives a diffraction relief.

The Examiner on page 4 states "cellulose such as HPMC is thermoformable." Applicant is not aware of such a teaching in the prior art of record. The article and the Rule 132 Declaration at para. 11 state that experiments were run on heat stamping hard candy mixed with fats and starches. There is no teaching of heat stamping of HPMC per se. Indeed, the Rule 132 Declaration as a whole points out that it was anything but obvious to an actual skilled person in the art at the time of the invention that any material forming a pharmaceutical dosage form could receive a microscopic, light-wave-dimensioned diffraction relief, release from a forming element while

preserving the pattern, retain the formed shape, and do so over the product life of a pharmaceutical, and without the admixture of other materials.

While the Examiner argues on page 4 that the references suggest a combination of Begleiter I and II to reach the presently claimed invention, this argument does not address that 1) this prior art teaches away from any such combination, and 2) there is no teaching, suggestion or motivation in the cited art to make this combination. Again, the references direct one to use cold pressing powders to create pharmaceuticals having the ability to produce holographic images and effects. The prior art mentions HPMC and other complex polysaccharides, but only to form dehydrated films for use on confections and like foodstuffs. The prior art teaches plasticizers, but not in the presently claimed combination for the presently claimed purpose.

The Examiner also argues obviousness on page 4 bottom, page 5 top. Begleiter II is cited as teaching "kid vitamin candy," argued as "pharmaceutical dosage forms." But this cited references in Begleiter II is in the part of Begleiter II teaching that for pharmaceuticals, one does not use Begleiter I teachings, instead one compresses a powder.

As stated in the Rule 132 Declaration, para. 9, pressing a powder by itself in a tablet press to pick up a hologram that is a part of the punch had a number of serious commercial problems such as the punch/diffraction grating wearing out very quickly ("wore out within a few cycles") or becoming clogged after a few tries; also the tablet did not have good brightness or stability (in contrast to the description of stable in the present specification).

The claimed invention defines a product using a material that can be applied to a tablet. The layered tablet can then be handled, and that rapidly flows and sets at just the correct time, all while picking up the fine grating structure (but importantly not clogging or destroying the transfer plate, releasing from the impression plate for the next cycle to begin), and then holding a hologram with high diffraction efficiency (bright) in a stable or controllable way.

This is very different from the prior art disclosures of casting elements or altering the punch in a standard tablet press using a standard tablet powder.

With respect to the Examiner's comments with respect to the Rule 132 Declaration, Applicant is not aware of any requirement that such a Declaration must have any specific form. It need only present facts, not opinion, and be responsive to the rejection(s) MPEP 716. The facts can be directed to any of the *Graham vv. Deere* primary or secondary considerations.

Here, the cited prior art is Applicant's own work. Moreover, as detailed in the Declaration, Applicant believes that he is the pioneer in applying holographic patterns on edible products, and now on pharmaceuticals. The Declaration presents facts about technical problems, failed experiments, product performance, skepticism of third parties, long felt need, commercial success, and addresses the teachings of the prior art and the obviousness of the present claims.

Whether or not any material could be thermoformed to produce a diffraction relief in a layer of a pharmaceutical dosage form was not obvious to the Begleiter of Begleiter I and Begleiter II. Moreover, the Declaration provides facts from the person most knowledgeable about the products produced under the teachings of Begleiter I and Begleiter II as to the performance of those products and their suitability as pharmaceutical dosage forms. The prior art images faded rapidly. Begleiter II directly states that the holographic images and effects created by it teachings did not last beyond 9 months. The Declaration provides specifics, "data." It notes "conditions" such as prior art images produced in cold compressed tablets as disappearing when breathed upon (para. 11). In the same paragraph, it describes prior art heat stamping of reliefs on hard candy materials as producing images that "lasted only a few weeks, even under perfect conditions." (emphasis supplied) "Stable" as used in the claims is defined in the specification. Pharmaceutical markings clearly must be stable -- last much longer than the stated durability of the Begleiter I and Begleiter II images and effects.

The Declaration details reasons for this stability problem, including the affinity of sugar products for moisture and its deleterious effect at image stability. Again, the cited prior art taught that one had to go to a new approach to create a holographic pharmaceutical – a cold compress tablet. That, however, was a failed experiment, as delineated in the Declaration.

With respect to the dependent claims, it is axiomatic that each claim defines a separate invention. *Jones v. Hardy*, 727 F.2d 1524, 220 USPQ 1021 (Fed.Cir. 1984). The dependent claims define significant, novel, non-obvious features. The Examiner, at page 6, appear to say that because she has rejected the claim from which they depend, there is some special burden on Applicant to prove the patentability of the combination of features of the dependent claims. Previous responses have discussed specific claimed features and noted their patentability regardless of the patentability of the claim from which they depend. Applicant is not aware of any citations to the prior art teaching or suggesting the claimed combinations of these dependent claims.

To recap certain of these dependent claims, they include: claims 3, 5, 19-24 relating to a pharmaceutical dosage form that responds controllably to temperature and/or humidity to provide a visual indication of the environmental history and efficacy of the dosage form; claims 15 and 16 relating to a heat fusion bond between the outer layer and a core; claim 17 relating to the outer layer constituting a capsule; the "strip" dosage form of claim 18; the use of waxes in a layer forming a diffraction relief to control the response of the relief to temperature (claims 11, 12/11, 13/12, 16, 20, and 21); as well as claims 25-28 relating to features of a pharmaceutical dosage form of the present invention that also resists twinning.

In view of the foregoing Remarks, Applicants urge that the pending clams define clear cut and significant patentable differences over the prior art, whether taken alone or in any combination, and that his application is otherwise in condition for allowance.

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Respectfully submitted,

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